

DMR

Display Date	8.19.99
Publication Date	8.23.99
Certifier	SNRESE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P-0683]

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document as a reproposal of one provision of its proposed rule of November 10, 1998, entitled "Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease." In that proposal, FDA tentatively indicated its intention to use a specific analytical method to measure soy protein for assessing compliance. Comments on that proposal argued that that method is inadequate for many products. FDA is therefore proposing an alternative procedure that will rely on measurement of total protein and require manufacturers, in certain circumstances, to maintain records that document the amount of soy protein in products and to make those records available to appropriate regulatory officials for inspection and copying upon request.

DATES: Written comments by (*insert date 30 days after date of publication in the Federal Register*). See section VI of this document for the effective date of any final rule that may issue based upon this proposal.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB,

New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Susan M. Pilch, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4500.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101-535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they provided procedures whereby FDA is to regulate health claims on food labels and in food labeling.

In the **Federal Register** of January 6, 1993 (58 FR 2478), FDA issued a final rule that implemented the health claim provisions of the act. In that final rule, FDA adopted § 101.14 (21 CFR 101.14), which sets out the rules for the authorization and use of health claims. Additionally, FDA established in § 101.70 (21 CFR 101.70) a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(f)).

In the **Federal Register** of November 10, 1998 (63 FR 62977), FDA proposed adding § 101.82 to authorize the use, on food labels and in food labeling, of health claims on the association between soy protein and reduced risk of coronary heart disease (CHD) (the soy protein proposed rule). FDA proposed this action in response to a petition filed by Protein Technologies International, Inc. (the petitioner) (Refs. 1 and 2). In the soy protein proposed rule, the agency presented the rationale for a health claim on this substance-disease relationship as provided for under the standard in section 403(r)(3)(B)(i) of the act (21 U.S.C. 343(r)(3)(B)(i)) and § 101.14(c) of FDA's regulations. The agency tentatively concluded that, based on the totality of publicly available

scientific evidence, soy protein included in a diet low in saturated fat and cholesterol may reduce the risk of CHD. The soy protein proposed rule included qualifying criteria for the purpose of identifying soy protein-containing foods eligible to bear the proposed health claim and a proposed method for assessing compliance with the qualifying criteria.

The petitioner requested that measurement of total soy isoflavones be used as a marker for the content of soy protein in foods and as an indicator of the effectiveness of soy protein products in reducing blood cholesterol levels. As discussed in section III.C.5 of the soy protein proposed rule (63 FR 62977 at 62987 to 62988), FDA found that the petitioner's conclusions regarding the significance of soy isoflavones with respect to the observed cholesterol-lowering effects of soy protein were not supported by the available studies. Thus, in section V.C. of the soy protein proposed rule (63 FR 62977 at 62992), FDA found the petitioner's proposed methodology to assess isoflavones was not suitable for assessing whether foods contain sufficient soy protein to be eligible to bear the health claim. Accordingly, in § 101.82(c)(2)(ii)(B), FDA proposed to measure soy protein for compliance purposes using the Association of Official Analytical Chemists International (AOAC) official method of analysis No. 988.10. This AOAC method is an enzyme-linked immunosorbent assay (ELISA) that can detect soy protein in raw and heat-processed meat products. With this assay, samples are compared to standard commercial soy protein and appropriate blanks. The sample extraction procedure, which involves preparation of an acetone powder, has been shown to be appropriate for a complex food matrix (meat). FDA tentatively concluded that this assay also should be suitable for other food matrices and requested comments on the suitability of this method for assuring that foods bearing the health claim contain qualifying levels of soy protein.

II. Assessing Qualifying Amounts of Soy Protein in Foods

In response to the soy protein proposed rule, the agency received approximately 130 letters, each containing one or more comments, from consumers, consumer organizations, professional organizations, government agencies, industry, trade associations, health care professionals, and research scientists.

Several of the submissions included comments about the analytical method that FDA had proposed to assess the qualifying levels of soy protein. All of these comments disagreed with the proposed approach to assessing compliance, and some suggested alternative approaches. The agency is addressing only the comments about the analytical method and compliance assessment in this document.

A. Comments on the Proposed Analytical Method

All of the comments on the proposed analytical method disagreed with the use of AOAC official method of analysis No. 988.10 and concluded that this ELISA method was unlikely to produce a reliable measure of the soy protein content of foods in all cases. Several comments noted that the method was designed and validated (Refs. 3 and 4) for the detection of soy protein in raw and cooked meat products. They also noted that numerous factors affect the quantitative results obtained and reported that published and unpublished data indicated that the assay can usually only be considered semi-quantitative.

The comments pointed out several problems with the assay including:

(1) Different soy protein sources and methods of processing (defatted flours, isolates, concentrates, products subject to hydrolysis or extrusion) can yield different response factors to the immunoassay (Refs. 4 through 7).

(2) Heating the sample can induce loss of response (Ref. 5).

(3) Only a small number of matrices have been tested for interference with soy protein quantitation. Although most of these were relatively low (Refs. 4 and 5), other vegetable and cereal sources of protein have the potential for considerable interference and need to be tested.

(4) The collaborative study of the method in meat products containing few or none of the potential interferents indicated a between-laboratory variability of approximately 30 percent (Ref. 6).

One comment noted that the need to have available a sample of the specific soy protein ingredient used in the product for calibration (Ref. 7) in order to have a quantitative method posed

difficulties in the practical use of the assay. Because many foods contain more than one soy protein ingredient that may be processed differently, use of the assay would require manufacturers to maintain samples and product specification sheets for possible later analysis. Another comment noted the expense of validating the method for each soy protein source and each product produced.

The agency is persuaded by these comments that AOAC official method of analysis No. 988.10 is not an appropriate method for the quantitation of soy protein in many of the products that may be eligible to bear the health claim. Therefore, FDA will not be adopting its use to assess compliance in the final rule.

B. Alternatives for Assessing Compliance

Some comments urged that FDA consider use of other validated ELISA methods. One published variation on the ELISA procedure (Ref. 8), like the method that FDA had initially proposed, has been validated only in meat products. Other ELISA assay techniques described in a comment were reported to be proprietary. Without validation data on such procedures, FDA is not proposing their use.

Several of the comments urged FDA to work collaboratively with other interested parties to develop an analytical method to quantify soy protein in various foods. FDA agrees that having a reliable, accurate analytical method is the ideal means to verify compliance. The agency intends to pursue development of an analytical method for soy protein and would be open to a collaborative effort with industry similar to that undertaken to develop a methodology to measure folate. However, FDA's resources are limited. Moreover, the complicated nature of the analytical problem may take several years to solve. (The agency notes that it took FDA and the industry over 10 years to develop a highly specific antibody for use in the analysis of free folic acid, a task that was relatively simple compared to developing a methodology to measure soy protein in all foods.) Development of a universally applicable analytical method, or multiple methods applicable to different foods or soy protein sources, to measure soy protein in foods is not likely to provide a timely, practical method to assess compliance. Accordingly, the agency is not prepared to

authorize use of a soy protein health claim based on use of analytical methodology that does not now exist. Should, however, suitable analytical methodology for soy protein be developed and validated, the agency would propose to amend its regulation to provide for use of such method or methods for compliance verification.

Several comments suggested alternative approaches to measure soy protein. These alternatives involved either calculations based on manufacturers' records or a combination of analysis of total protein content and calculations based on manufacturers' records. One comment noted that some of the soy-based foods that may be eligible to bear the health claim are products whose protein content is derived solely from whole soybeans or from soy protein ingredients such as soy flour, concentrates, or isolates. For such products, the amount of soy protein present is represented by the total protein content, for which an appropriate AOAC method as specified in § 101.9(c)(7) (21 CFR 101.9(c)(7)) is available. For other products that contain protein sources other than soy, the soy protein content would represent a calculable fraction of the total protein content. This comment noted that, based on the known amount of protein per gram of a soy ingredient (soy flour, concentrate, or isolate), one can calculate the quantity of soy protein in a final food product based on the known ratio of added soy products multiplied by the measured protein content. Another comment suggested that an alternative approach could consist of measurement of total protein content followed by calculation, through recipes, of soy protein content based on the ratio of soy protein to total protein in the food. The ratio of soy protein ingredients to total protein ingredients could be determined by reference to nutrient data bases, recipes, purchase orders for ingredients, or other reasonable bases. This comment further noted that the methodology and records that provide appropriate documentation for the calculations required should be available at the food manufacturer's facility or other site for review by FDA investigators. One comment endorsed the outlined approach of employing appropriate record keeping under FDA inspection for assessing compliance. Another comment recommended the use of manufacturing records for tracking both the presence and amount of soy protein in products bearing the soy protein health

claim. It further suggested use of such records would provide an accurate and practical method to determine the quantity of soy protein in a food. One comment supported a procedure whereby manufacturers would monitor the level of soy protein addition via batch recordkeeping that the agency would be able to inspect. Another comment recommended that those companies making the claim be responsible for tracking systems based on formulations and usage.

These comments have persuaded the agency that it should propose an alternative approach for quantifying soy protein in foods until such time as a suitable analytical method for soy protein is available. The agency is persuaded that a procedure employing measurement of total protein and, for some products, calculation of the soy protein content based on information contained in manufacturers' records is an accurate and practical method for assuring that products bearing the proposed health claim meet the requirement for the qualifying level of soy protein. FDA is, therefore, revising proposed § 101.82(c)(2)(ii)(B) to provide for this alternative approach for compliance assessment. Under this proposed approach, FDA will measure total protein in a product by an appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International," as described at § 101.9(c)(7). If the protein content per reference amount customarily consumed (RACC) fails to meet the qualifying level of soy protein for eligibility to bear the health claim, the product would not be in compliance with § 101.82 and would be misbranded under section 403(a) of the act. If the protein content per RACC equals or exceeds the qualifying level of soy protein and the food contains no sources of protein other than soy, the product would be in compliance with § 101.82. If the protein content per RACC equals or exceeds the qualifying level of soy protein and the food contains a source or sources of protein in addition to soy, then FDA will require that it have access to manufacturers' records to calculate the contribution of soy protein to the total protein content as the means to establish compliance.

C. FDA Inspection of Records

FDA is proposing a method to assess compliance for products that bear the proposed soy protein health claim that would require records inspection in some instances.

When Congress enacted the 1990 amendments, it sought to ensure that the rules pertaining to health and nutrient content claims would be enforceable (see H. Rept. 538, 101st Cong., 2d sess. 8, 9 (1990)). Health and nutrient content claims are intended to make the consumer aware of the nutritional attributes of the labeled food. Because these claims are meant to help consumers maintain healthful dietary practices, it is of the utmost importance that they accurately reflect the nutritional composition of the labeled food. (See 136 Congressional Record, H 12953, October 26, 1990, statement of house floor managers: “There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims.”)

Under section 701(a) of the act (21 U.S.C. 371(a)), the agency may issue regulations for the efficient enforcement of the act. Courts have recognized that FDA may impose recordkeeping requirements where they effectuate the act’s goals. (See *Toilet Goods Association v. Gardner*, 387 U.S. 158, 163–64 (1967); and *National Confectioners Association v. Califano*, 569 F.2d 690, 693 & n.9 (D.C. Cir. 1978).) The agency has required that records be maintained and made available for inspection by FDA employees in a number of situations. (See, e.g., 21 CFR 108.25(g) and 114.100 (acidified foods); 108.35(h) and 113.100 (thermal processing of low-acid foods); 129.80(h) (bottled drinking water); 172.320 (amino acids); 176.170 (components of paper and paperboard in contact with aqueous and fatty foods); and 179.25(e) (food irradiation).)

In addition, on a number of occasions, FDA has determined that adequate enforcement of labeling rules would be possible only if the agency can review the information that a manufacturer has developed to support the statements on its food labels. For example, in the final rule on serving sizes (58 FR 2229 at 2271, January 6, 1993), FDA provided that manufacturers of aerated foods could substitute a volume-based measure for a weight-based reference amount as the basis for determining a product’s serving size. Under the regulation (§ 101.12(e)(21 CFR 101.12 (e)), manufacturers who choose this approach must make available to the agency upon request certain information, including a detailed protocol and records of all data used to arrive at the density-adjusted reference amount (58 FR 2272). In the nutrient content claims final rule

(§ 101.13(j)(1)(ii)(A)), FDA also imposed a records requirement on firms that use a broad-based reference nutrient value for claims such as “light” (58 FR 2302 at 2365, January 6, 1993). In the **Federal Register** of February 2, 1996 (63 FR 3885), FDA proposed to extend record inspection requirements, in certain circumstances, to records that support the use of certain health claims and nutrient content claims. In that proposed rule, the agency specifically identified concerns about claims that are based on information about a food that is available only to the food manufacturer and without which the agency would be unable to evaluate the truthfulness of the claim (63 FR 3885 at 3887). In that proposed rule, the agency also discussed in detail its legal authority to issue regulations for the efficient enforcement of the act, including regulations that require that access to certain records be provided to the agency (63 FR 3885 at 3888 to 3889).

In the absence of an accurate and reliable analytical method for the quantitation of soy protein, when soy is not the only source of protein in a food, only the manufacturer will have the information required to determine the amount of soy protein per RACC. Therefore, FDA has tentatively concluded that the proposed requirements, which would cover only the proposed soy protein health claim, are necessary for the efficient enforcement of the act. Ensuring the accuracy of claims was an overriding concern of Congress in passing the 1990 amendments. Congress envisioned that, under the act as amended, “only truthful claims may be made on foods” (136 Congressional Record H 12953, October 26, 1990, statement of Representative Waxman).

A manufacturer who places a health or nutrient content claim in food labeling must have knowledge that the food qualifies to bear the claim. Congress expected that manufacturers would have to ascertain the nutritional attributes of their food products, through laboratory analysis or otherwise, in order to label those products properly. FDA has stated previously that a food manufacturer is responsible for the accuracy of its food labels (58 FR 2079 at 2163 and 2165). Indeed, a claim in food labeling that calls the consumer’s attention to the food’s nutritional characteristics is a representation that the manufacturer has evidence that the food meets the

requirements for the claim. Thus, making a claim without such a basis would be misleading, in violation of section 403(a) of the act.

FDA, therefore, proposes to require that, in some cases, manufacturers who choose to place a soy protein health claim on the food label or in labeling may do so only if they maintain the information on which the claim is based and make it available for inspection and copying to appropriate regulatory officials upon request. Failure to meet the requirements by maintaining appropriate records and complying with an agency request to examine those records will be a violation of section 403(r) of the act, misbranding the food bearing the claim.

Compliance with the proposed regulation should not entail the creation of any new information or the compilation of any special records. Rather, the proposed recordkeeping requirement would obligate manufacturers to keep and provide FDA with information that they should already possess. Adequate records may consist of results of appropriate combinations of direct product analyses, data base values, recipe calculations, and purchase orders.

The agency anticipates that manufacturers may have concerns about the confidentiality of the information inspected by the agency under this proposal. Manufacturers should be assured that FDA does not and would not release information that would provide a competitive advantage to another manufacturer (§ 20.61 (21 CFR 20.61)). For example, if a company's records that support the validity of the use of the soy protein health claim in a food's labeling contain confidential information describing product formulation, manufacturing processes, or unique testing methods, the agency would protect this information from public disclosure (§ 20.61). (See also 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 45 CFR 5.65.)

The agency notes that, if it does not proceed with this proposal to require access to records to verify the amount of soy protein in foods whose labeling bears a soy protein health claim, it is prepared to authorize use of the claim only on foods whose sole source of protein is from soy. However FDA ultimately proceeds, the agency would propose to amend its regulation to

provide for compliance verification based on one or more validated analytical methodologies that are effective in all foods, should such a methodology or methodologies be developed.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

In the analysis of the soy protein proposed rule, FDA examined the rule's effects under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). The agency found that the soy protein proposed rule was not a significant regulatory action under the Executive Order, and that it would not have a significant economic impact on a substantial number of small entities. This proposed modification of the method of assessing compliance does not change those conclusions.

In the following analysis, the agency discusses the benefits and costs associated with the proposed modification and three regulatory alternatives. The four options considered are:

1. Take no action (do not modify proposed method of assessing compliance in the soy protein proposed rule).
2. Modify proposed method of assessing compliance in the soy protein proposed rule as proposed in this document.
3. Use manufacturing records for all products as the method of assessing compliance.
4. Authorize use of the soy protein health claim only on foods whose sole source of protein is from soy.

A. Option One: Take no action (do not modify method of assessing compliance in the soy protein proposed rule)

Taking no action would not affect the actual costs or benefits of the soy protein proposed rule.

B. Option Two: Modify proposed method of assessing compliance in the soy protein proposed rule as proposed in this document

The specification of the method that FDA will use to determine the level of soy protein in products does not lead to additional compliance costs. Use of the proposed soy protein health claim is voluntary; manufacturers choosing to make the claim must determine the level of soy protein in their products, but need not use the same method that FDA proposes to use.

As discussed in section II.B. of this document, some comments on the soy protein proposed rule suggested alternative methods that FDA could use to determine the level of soy protein in products bearing the proposed claim. Having considered these comments, FDA is proposing to modify proposed § 101.82(c)(2)(ii)(B) to provide that FDA will establish the level of soy protein by analyzing the total protein content of a product by an appropriate method of analysis as given in the “Official Methods of Analysis of the AOAC International” as described in § 101.9(c)(7). If the product contains sources of protein in addition to soy, the agency will establish the level by using manufacturers’ records to calculate the contribution of soy protein to the total protein content.

1. Costs

The proposed modification may reduce the cost to FDA of determining the level of soy protein in some products. This cost is a social cost in the sense that FDA operating funds are derived from public tax revenues. Because this cost is not a compliance cost, reducing it will not affect the compliance costs of the rule but it may increase the net benefits—the costs of implementing a voluntary program must be subtracted from the benefits of that program in order to arrive at net benefits.

As discussed in section II.A. of this document, some of the comments on the method of compliance in the soy protein proposed rule indicated that its use would be costly for some

manufacturers. This proposed modification will reduce these distributive effects of the soy protein proposed rule, and so eliminate the equity issue raised in those comments.

2. Benefits

As discussed in section II.A. of this document, some of the comments on the soy protein proposed rule argued that the method for assessing compliance set forth in that proposal is not appropriate for the quantitation of soy protein in many of the products that may be eligible to bear the health claim. Use of that method would therefore reduce the information value of the health claim. This proposed modification would increase the information value of the health claim by increasing the accuracy of the statement concerning the level of soy protein in particular products.

The proposed modification might also reduce the benefits of the soy protein proposed rule if the requirement that FDA have access to records under the modified method were to discourage use of the proposed health claim and reduce the number of products bearing the claim. In some comments, firms indicated that the agency should use records to assess compliance, so the agency believes that many firms would still be prepared to use the claim on their food products. Most firms probably already keep the relevant records for business purposes, including: (1) Product recipes and formulations in order to make consistent products, (2) nutrient analyses or databases in order to comply with the required Nutrition Facts panel, and (3) purchase orders for normal business purposes. Therefore, the agency does not believe that the proposed modification will significantly reduce the benefits of the proposed health claim. FDA requests comments on whether, and the extent to which, the proposed modification would discourage use of the claim.

C. Option Three: Use manufacturing records for all products as the method of assessing compliance

As discussed in section II.B. of this document, FDA believes that there is no validated analytical method currently available that the agency could use instead of the analytical method proposed in the soy protein proposed rule. However, some comments on the soy protein proposed

rule recommended that FDA use manufacturing records for all products, not merely for those products that contain protein from sources other than soy.

1. Costs

Using manufacturing records in all cases would generate higher costs for FDA than using the proposed modified method for products that have only one source of protein. It would cost more to use manufacturing records to determine the level of soy protein in products whose only source of protein is soy than it would cost to determine the level of soy protein in those products by using only an appropriate analytical method.

2. Benefits

Using manufacturing records in all cases may reduce the benefits of the soy protein proposed rule more than the proposed modified method, if more manufacturers would be discouraged from using the claim because they would be required to provide FDA with access to their records.

D. Option 4: Authorize use of the soy protein health claim only on foods whose sole source of protein is from soy

As stated in section II.C. of this document, if FDA does not proceed with the proposed modified method to verify the amount of soy protein in some foods using records, it is prepared instead to authorize use of the claim only on foods whose sole source of protein is from soy. Under this option, fewer products would be able to make claims under the soy protein proposed rule. The costs and benefits of the rule would therefore be less than under the modification proposed in this rule.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. A description of these requirements is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information; including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Title: Record Retention Requirements for the Soy Protein/CHD Health Claim

Description: Section 403(r) of the act requires that food bearing a health claim authorized by regulation on a petition to the agency be labeled in compliance with that regulation issued by FDA. In the soy protein proposed rule (63 FR 62977 at 62994), FDA stated its tentative conclusion that the labeling requirements proposed for soy protein are not subject to review by OMB because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the proposed food labeling health claim on the association between soy protein and reduced risk of CHD would be a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)). The regulation set forth in this proposed rule would authorize the use in food labeling of a health claim about the relationship between soy protein and CHD. This proposal would also require that a manufacturer of a product bearing the proposed soy protein health claim whose product contains non-soy sources of protein retain all the records that permit the calculation of the ratio of soy protein to other sources of protein in the food. The manufacturer of such a food product would be required to make those records available for review and copying by appropriate regulatory officials upon request and during site visits.

Description of Respondents: Businesses or others for-profit.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

¹ There are no capital costs or operation and maintenance costs associated with this collection of information.

FDA believes that the records that a manufacturer would retain would be records that a prudent business would obtain and retain as a normal part of doing business. The requirements contained in this proposal would require only a minimal burden, no more than one hour per response, from respondents.

In compliance with 44 U.S.C. 3507(d), the agency has submitted the information collection requirements of the proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by *(insert date 30 days after date of publication in the Federal Register)* to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

VI. Proposed Effective Date

FDA is proposing to make these regulations effective upon publication in the **Federal Register** of a final rule based upon this proposal.

VII. Comments

Interested persons may, on or before *(insert date 30 days after date of publication in the Federal Register)*, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This proposed rule is not a “technical regulation” as defined in 19 U.S.C. 2576b(7) because it is not mandatory that a soy protein health claim be placed on the label or in the labeling of qualifying foods. Therefore, the requirement for a 75-day comment period for a proposed technical

regulation found in Executive Order 12889, “Implementation of the North American Free Trade Agreement,” does not apply to this proposed rule. In addition, this proposal addresses only the narrow issue of the method FDA will use to verify that foods bearing a soy protein health claim contain the required amount of soy protein. Moreover, under section 403(r)(4)(A)(i) of the act, if the agency issues a proposed regulation on a health claim petition, the agency is to complete the rulemaking within 540 days of the date the agency receives the petition (see also § 101.70(j)(4)(ii)). Therefore, FDA finds that there is good cause under 21 CFR 10.40(b)(2) to provide 30 days, rather than 60 days, for public comment on this proposed rule.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Protein Technologies International, Inc., “Health Claim Petition,” May 4, 1998 [CP1, vol. 1–3]
2. Protein Technologies International, Inc., “Addendum to Health Claim Petition,” August 10, 1998 [CP1, vol. 4]
3. Crimes, A. A., F. J. Bailey, and C. H. S. Hitchcock, “Determination of Foreign Proteins in Meat Products,” *Analytical Proceedings*, 18:164–166, 1981.
4. Hitchcock, C. H. S., F. J. Bailey, A. A. Crimes, D. A. G. Dean, and P. J. Davis, “Determination of Soya Proteins in Food Using an Enzyme-linked Immunosorbent Assay Procedure,” *Journal of the Science of Food and Agriculture*, 32:157–165, 1981.
5. Griffith, N. M., M. J. Billington, A. A. Crimes, and C. H. S. Hitchcock, “An Assessment of Commercially Available Reagents for an Enzyme-linked Immunosorbent Assay (ELIZA) of Soy Protein in Meat Products,” *Journal of the Science of Food and Agriculture*, 35:1255–1260, 1984.
6. Olsman, W. J., S. Dobbelaero, and C. H. S. Hitchcock, “The Performance of an SDS–PAGE and ELISA Method for the Quantitative Analysis of Soya Protein in Meat Products, an International Collaborative Study,” *Journal of the Science of Food and Agriculture*, 36:499–507, 1985.

7. McNeal, F. E., "Semiquantitative Enzyme-linked Immunosorbent Assay of Soy Protein in Meat Products: Summary of Collaborative Study," *Journal of the Association of Official Analytical Chemists*, 71(2):443, 1988.

8. Yasumoto, K, M. Sudo, and T. Suzuki, "Quantitation of Soya Protein by Enzyme-linked Immunosorbent Assay of its Characteristic Protein," *Journal of the Science of Food and Agriculture*, 50:377-389, 1990.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. In § 101.82, as proposed to be added at 63 FR 62977 at 62997, November 10, 1998, revise paragraph (c)(2)(ii)(B) to read as follows:

§ 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).

* * * * *

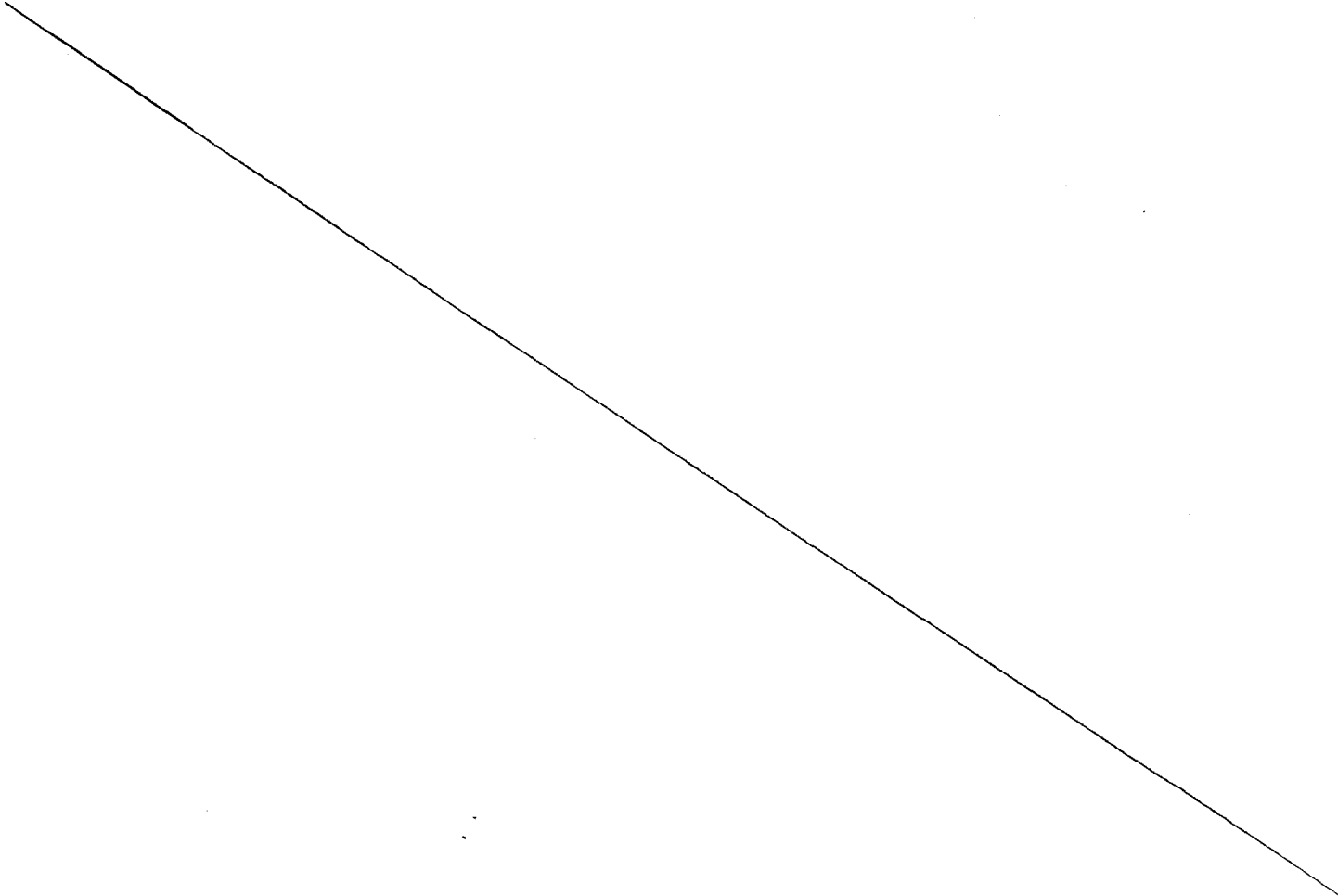
(c) * * *

(2) * * *

(ii) * * *

(B) FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the "Official Methods

of Analysis of the AOAC International,” as described at 21 CFR 101.9(c)(7). Interested persons can obtain copies of the “Official Methods of Analysis of the AOAC International” from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may examine copies at the Center for Food Safety and Applied Nutrition’s Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the **Federal Register**, 800 North Capitol St. NW., suite 700, Washington, DC. For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation of the ratio of soy protein ingredients to total protein ingredients on manufacturers’ information such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or other reasonable bases. Manufacturers must maintain records that permit such

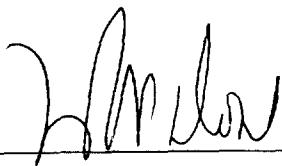


calculations for as long as the products are marketed. Manufacturers must make these records available for authorized inspection and copying by appropriate regulatory officials and manufacturers must submit these records to those regulatory officials upon request.

* * * * *

Dated: 8/16/99

August 16, 1999



Margaret M. Dotzel
Acting Associate Commissioner
for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

